REMARKS

I. Introduction

Claims 27, 28 and 44 - 58 are pending. Claims 27, 28 and 48 - 52 are finally rejected. Claims 27, 28, 44, 45 and 48 - 52 are rejected under 35 U.S.C. § 112, first paragraph for failing to comply with the written description requirement. Claims 27 - 28 and 50 - 52 are rejected under 35 U.S.C. § 112, first paragraph for failing to failing to comply with the written description requirement. Claims 27, 28, 44, 45, and 48 - 52 are rejected under 35 U.S.C. § 112, second paragraph, for being indefinite. Claims 46, 47, and 53 - 58 are allowed.

Claims 27, 44, 46, 50 and 51 are amended. New claims 59 -62 are presented. For the amendment to claim 27 and new claims 59 - 62, support can be found throughout the specification and claims as originally filed, e.g., pages 2, 3, 13, examples 6, 7, 11 and 12, and accompanying figures, describing C140 structure and biological function. Claim 27 has been amended to correct a typographical error, and claim 46 has been amended to better clarify the invention. It is believed no new matter has been added.

The Examiner has required the submission of a substitute computer readable form of the sequence listing previously submitted by the Applicants in which errors were detected by the USPTO. Applicants response to the Notice to Comply with the Sequence Rules is submitted concurrently herewith.

II. 35 U.S.C. Section 112, first paragraph Rejections

Claims 27, 28, 44, 45 and 48 - 52 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, that the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner asserts that the C140 receptor peptide having "cross-reactive antigenicity to at least 15 amino acids of the amino acid sequence of SEQ ID NO:4 or SEQ ID NO:63"

constitutes new matter. Applicants respectfully traverses the rejection. To facilitate prosecution, however, Applicants have amended claims 27 and 44 to delete the recitation. The description provides considerable detail as to the structure and function of the claimed polypeptides, and the claims are clearly defined structurally, with reference to proteins encoded by particular sequences and sequences hybridizing under defined conditions thereto. As the structure of the claimed polypeptides is not open-ended or otherwise undefined, there is no need for a functional limitation in the claim, the biological function (e.g., as a receptor or effector or as a polypeptide being useful to generate antibodies to C140) being inherent in the structure. The subject matter of the claims is thus clearly described and specifically claimed. Withdrawal of the rejection and allowance of claims 27, 44 and dependent claims thereon is respectfully requested.

III. 35 U.S.C. § 112, first paragraph rejections

Claims 27 - 28 and 50 - 52 were rejected under 35 U.S.C. § 112, first paragraph, that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner re-asserts the rationale in the Office Action dated April 6, 2005, that Applicants are not in possession of a genus, and the presentation of two species does not represent a sufficient number of species to describe the claimed genus because of the "broad definition of the genus of molecules which is encompassed by the term 'C140 receptor polypeptides'" and "the absence of information on the specific regions of the molecule responsible for specific biological activities of the molecule". The Examiner cites no authority or case law in support of his position. Applicant respectfully traverses this rejection and requests reconsideration.

Applicants re-assert their argument that the claimed subject matter is sufficiently described in the specification as filed. In *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559 (Fed. Cir. 1997) ("*Lilly*") , a leading case on written description in the context of biotechnology inventions, the patentee claimed a broad

classes of human, mammalian, and vetebrate insulin cDNA, but only disclosed *a single sequence* to rat insulin cDNA. Court of Appeals for the Federal Circuit held that claims to the broad genus were invalid because the "description of rat insulin cDNA is not a description of the broad classes of vertebrate or mammalian insulin cDNA. *Id.* at 1568. The specification and generic claims to all cDNAs encoding for vertebrate or mammalian insulin did not describe the claimed genus because *the patentee did not set forth any common features possessed by members of the genus* that distinguished them from others. *Id.* In contrast to *Lilly*, Applicants have characterized C140 for *both* mice and humans, and they have disclosed numerous structural features of C140. Applicants have identified C140 as being a member of the G-protein-coupled receptor family. G-proteins are well known in the art and many have been extensively characterized as having particular features in common, for example seven transmembrane domains which are connected by cytoplasmic and extracellular loops. Applicants have demonstrated conservation of these features and a high degree of homology between murine and human C140, *see e.g.*, figure 3. Applicants are not required to disclose every species even in an unpredictable art. *In re Angstadt,* 537 F.2d 498, 503 (C.C.P.A. 1976). Given the detailed structural characterization of the protein and gene from both mice and humans, coupled with the relatively advanced understanding and vast literature directed to the G-protein coupled receptor family, the disclosure that Applicants have provided in the specification provides ample description to permit one of skill in the art to appreciate and understand the claimed invention and to identify any protein that may fall within the limitations of the claims.

Generally, in accordance with claim 27, the claimed polypeptide of the present invention is any molecule which is encoded by a nucleic acid molecule which hybridizes under stringent conditions with either (a) a nucleic acid molecule complimentary to SEQ ID NO:3, or (b) a nucleic acid molecule complimentary to SEQ ID NO:62.

Stringent conditions for hybridization to the defined sequences are set forth in detail in the claim and specification. Applicants submit that the structural limitations of hybridization to defined sequences is by itself sufficient to convey to one skilled in the art

that the inventors had possession of the claimed genus. This is in contrast to the situation in *Lilly,* where there was *no* specific description of the sequence or structure of the claimed cDNA or the mRNA which encoded it. Thus the genus claimed in this case is both much narrower and much better defined than that claimed in *Lilly.* The Federal Circuit has made clear that hybridization to a defined sequence is sufficient to provide written description for a genus of hybridizing sequences. In *Enzo Biochem, Inc. v. Gen-Probe Inc., et al.,* 296 F.3d 1316 (Fed. Cir. 2002), for example, the Federal Circuit held that mere deposit of DNA in the form of a recombinant DNA molecule within an *E. coli* strain, even though not even actually sequenced, could provide adequate written description requirement to support claims to DNA of undefined function which hybridized to the deposited, unsequenced probes. In the present invention, Applicant's reference nucleic acid sequence is specifically defined, sequenced, and characterized, and Applicants respectfully submit that there should be no question as to the adequacy of the written description of the hybridizing nucleic acid sequences or the polypeptides inherently encoded by those sequences.

Applicants believe that the rejection of dependent claims 28 and 50 - 52 has also been addressed by correction of the base claim and respectfully requests withdrawal of the rejection of claims 27 - 28 and 50 - 52, and allowance of the same.

Applicants note that claim 44 (currently rejected for new matter) was rejected in the Office Action dated April 6, 2005 on a basis similar to that currently asserted against claim 27, but that that ground of rejection was not maintained in the last Office Action. It thus appears that the Examiner has withdrawn the previously asserted rejection of claim 44 relating to enablement of a genus. However, if this is not the Examiner's intention, Applicants respectfully submit that the above arguments apply equally to claim 44.

IV. 35 U.S.C. § 112, second paragraph rejections

A. Claim 27 (and dependent claims) were rejected because the phrase "polypeptide having a consecutive sequence of at least 15 amino acids" was considered to be unclear. Applicants appreciate the Examiner's suggestion of alternative language and have

accordingly amended the claim. Applicants respectfully request that the rejection be withdrawn and claim 27 and its dependent claims be allowed.

B. Claim 27 and 44 were rejected because the recitation of cross-reactive antigenicity to "at least 15 amino acids" was considered to be unclear. Claims 27 and 44 have been amended to delete the recitation, as it is not necessary to define the claims. Applicants respectfully requests that the rejection be withdrawn and claims 22 and 44 allowed.

C. Claim 50 and 51 were rejected because both claims refer to "either of" one sequence, which is obviously an error. The Applicant thanks the Examiner for identifying the errors in these claims, and has amended claims 50 and 51 to remove the phrase "either of". Accordingly, Applicant respectfully requests that the rejection be withdrawn and claims 50 and 51 allowed.

V. Sequence Listing

The Examiner has required the submission of a substitute computer readable form of the sequence listing previously submitted by the Applicants as per the Notice to Comply with the Sequence Rules/RAW SEQUENCE LISTING ERROR REPORT. Applicants hereby submit a substitute computer readable form of the sequence listing (2 compact disks) and a substitute paper Sequence Listing as well as a copy of the Notice to Comply and RAW SEQUENCE LISTING ERROR REPORT as provided in Applicant's Amendment under 37 CFR §§ 1.821 - 1.825 filed concurrently herewith.

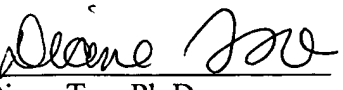
VI. Summary

All of the rejections have been addressed. Favorable consideration of the pending claims is respectfully requested. As this response is filed within two months of the Final Office Action, an advisory action is requested. Should the Examiner have any questions or concerns, he is invited to contact the undersigned.

It is believed no fee is necessary. If a fee is required, please charge the same to Deposit Account 50-3464.

Respectfully submitted,

Date: March 13, 2006

By 

Diane Tso, Ph.D.
Reg. No. 46,012
HOXIE & TSO LLP
374 Millburn Avenue
Suite 300E
Millburn, NJ 07041
(973) 467-2126